Quality Assessment of Drug Therapy

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Patient Concerns

Wrong medicine	61%
Drug interactions	58%
Cost of treatment	58%
Complications from procedure	56%
Hospital acquired infection	49%
Negative side-effect	49%
Too much medicine	49%
Suffering from pain	49%

ASHP Survey: July, 1999

Drug Related Morbidity and Mortality Costs

Hospital	$121 billion
Long Term Care	33 billion
Physician visits	14 billion
Emergency visits	5 billion
Added prescriptions	3 billion
Total	$177 billion

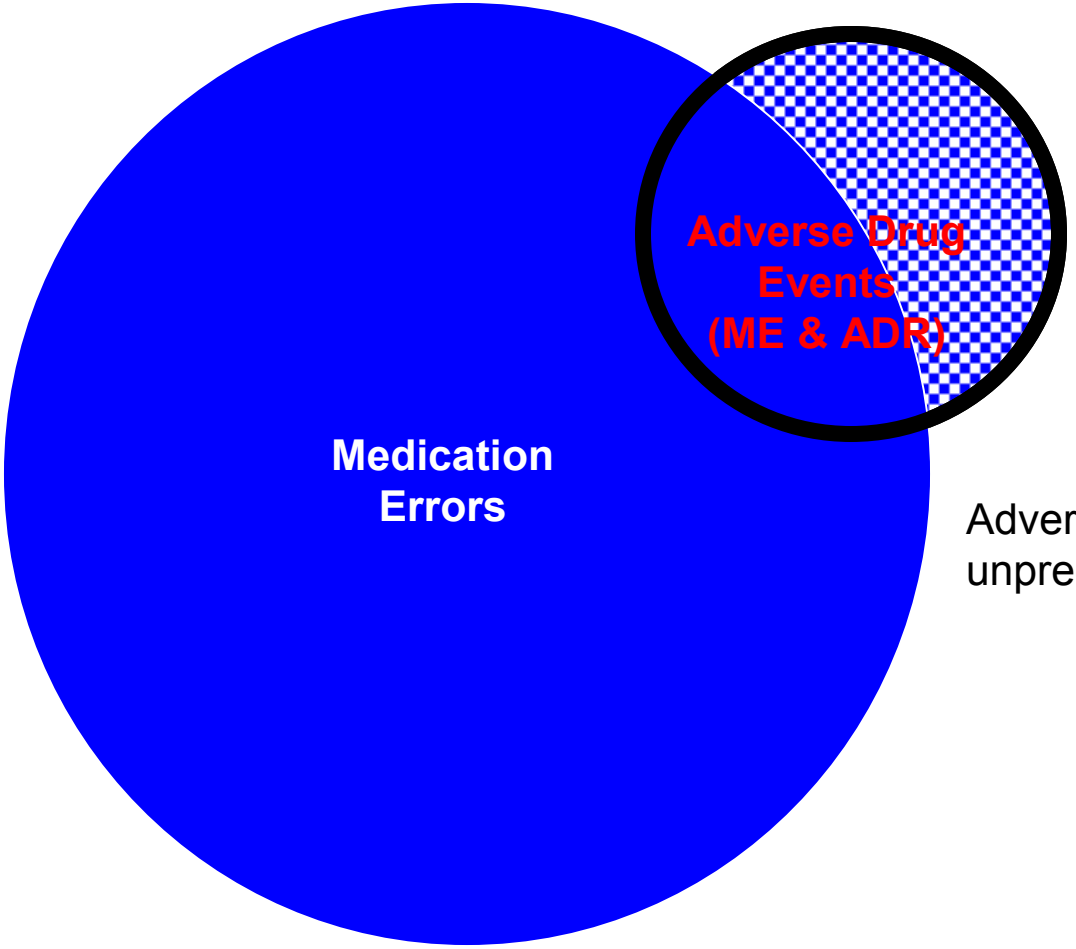
Ernst, J Am Pharm Assn. 2001; 41:192-9 (Mar 2001)

Medication Use Quality Issues

- Medication use process/system
- Organizational interests in med use
- Monitoring and improving med use quality
- Identifying and reducing med errors

Adverse Drug Events

Adapted from Bates et al.



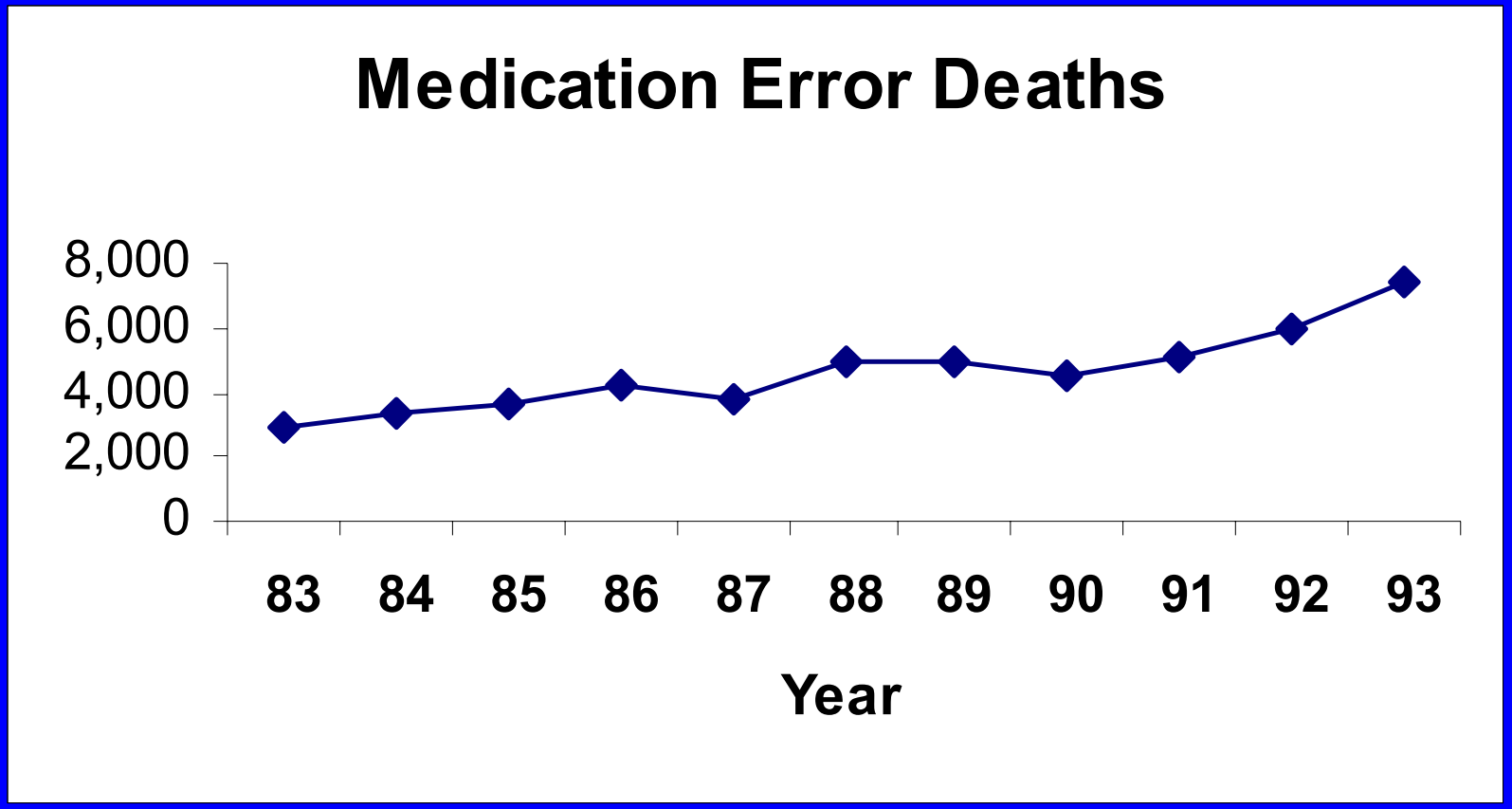
Adverse Drug Event: preventable and unpredicted event with harm to patient

Medication Errors

Any preventable event that may cause or lead to inappropriate medication use of patient harm while medication is in the control of the health care professional, patient or consumer

National Coordinating Council for

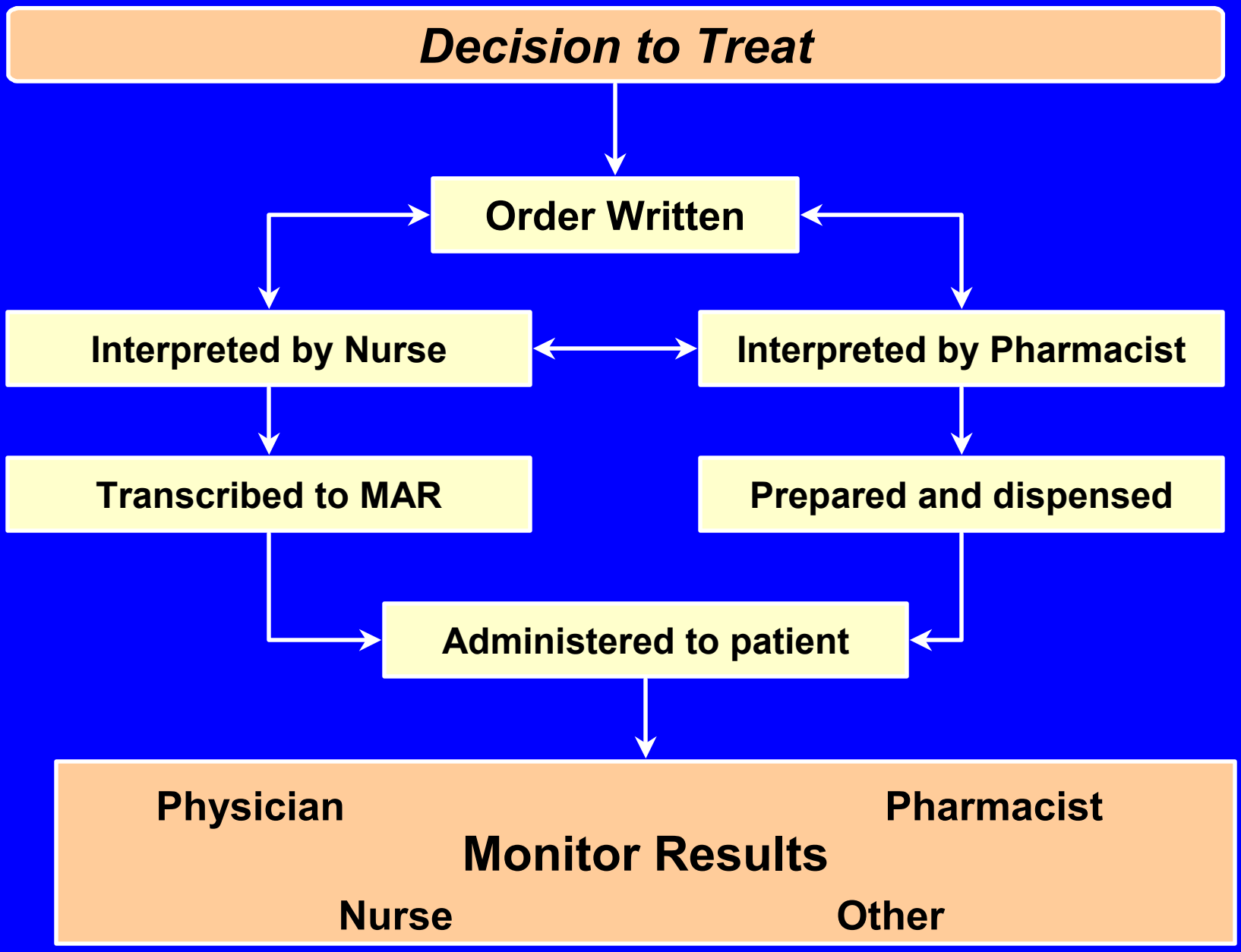
Medication Error Reporting and Prevention



Phillips DP, Christenfeld N, Glynn LM, The Lancet 1998; 351: 643-44

Cost Impact of ADE's

	Increased LOS	Increased Cost
ADE	2.2	$3,244
Preventable ADE	4.6	$5,857


Decision to Treat
Order Written
Interpreted by Nurse
Interpreted by Pharmacist
Transcribed to MAR
Prepared and dispensed
Administered to patient
Physician
Pharmacist
Monitor Results
Nurse
Other

Medication Use Process

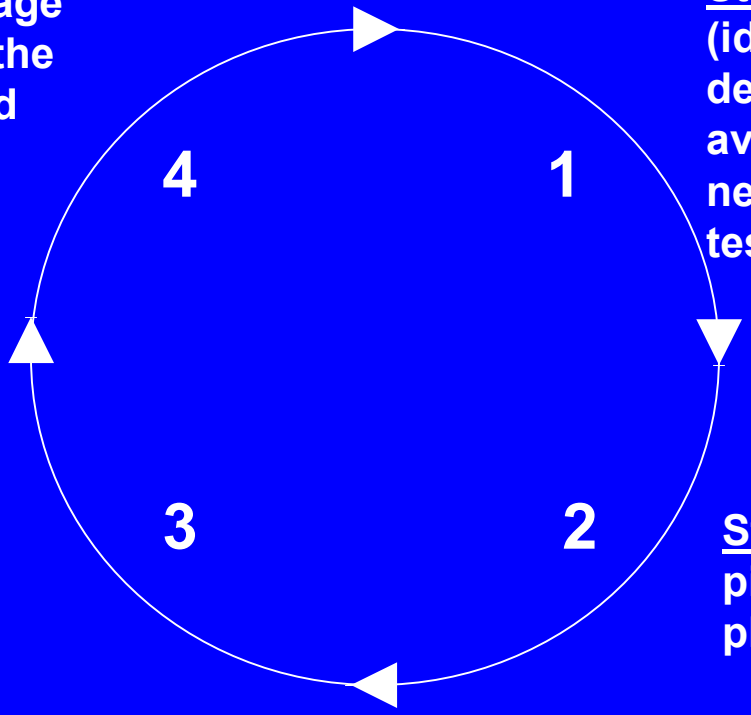
- Complex system
- Opportunities for error
- Impacts patient care and research

Process Improvement

- Continuous Quality Improvement
- Data driven
- System focused

Shewhart Cycle in Quality Improvement

Step 4: Evaluation stage (study the results of the changes implemented during this cycle)



Step 1: Planning stage (identify objectives, define data which may be available, define new data needs, plan change or test)

Step 3: Observation stage (collect information on the effect of the planned changes which have been implemented)

Step 2: Implementation or pilot stage (complete the planned changes or test)

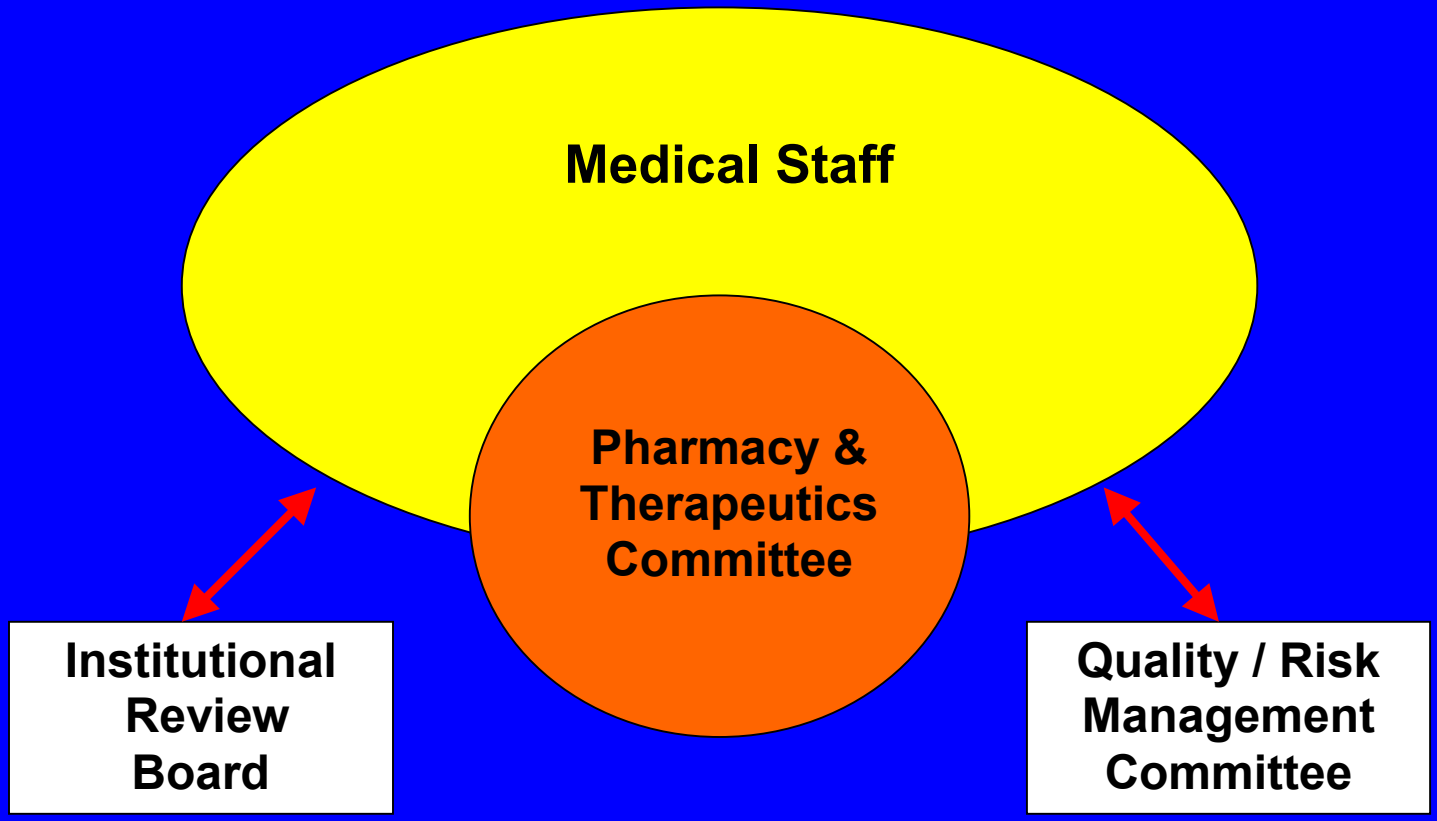
The Shewhart cycle is repeated over and over with desired improvements implemented with each new cycle, and results measured and used for next cycle

Organizational Interests

- What to use
- When to use it
- How to use it
- Is it cost-effective
- Will it be used safely

Pharmacy and Therapeutics Committee

Focus for medication related activities within a health care organization


Medical Staff
Pharmacy & Therapeutics Committee
Institutional Review Board
Quality / Risk Management Committee

P&T Committee Overview

- Medical Staff Committee
- Oversight of medication use in the organization
- Staff experts in the medication use process

P & T Committee Role

- Medication related policies
- Formulary drug selection
- Evaluate medication use and improve performance
- Educate

Medication Policy Issues

- Medication prescribing
- Medication selection and quality
- Medication administration
- Special issues

Formulary

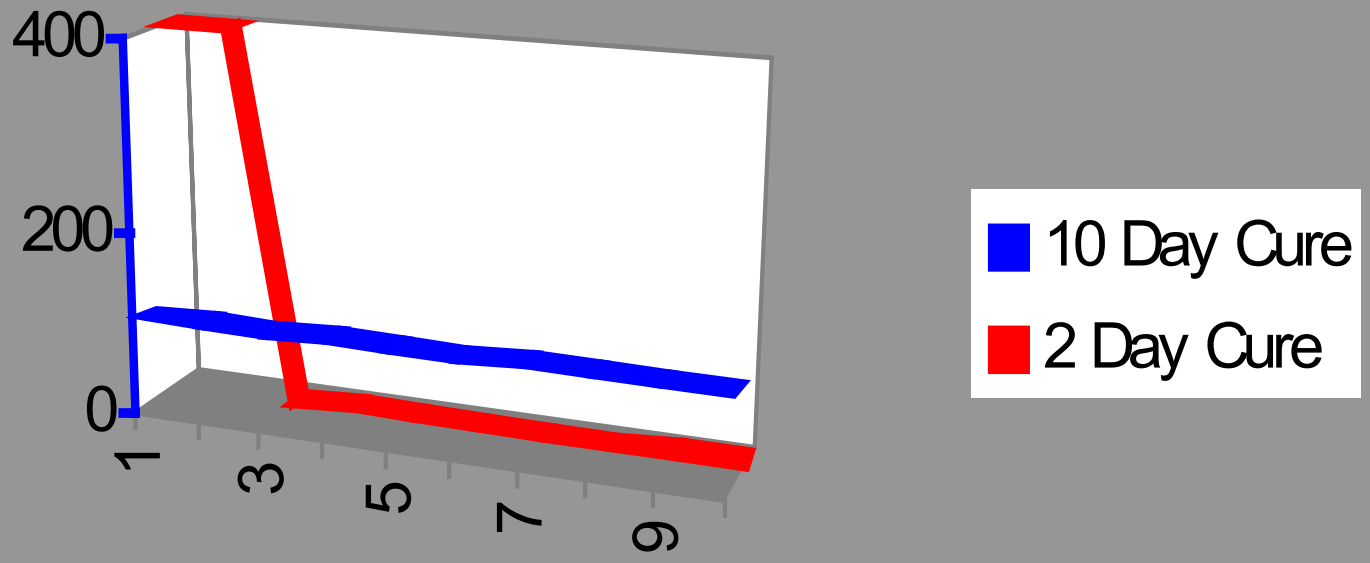
A continuously updated list of medications and related information representing the clinical judgement of physicians, pharmacists, and other experts…

Principles of a Sound Formulary System

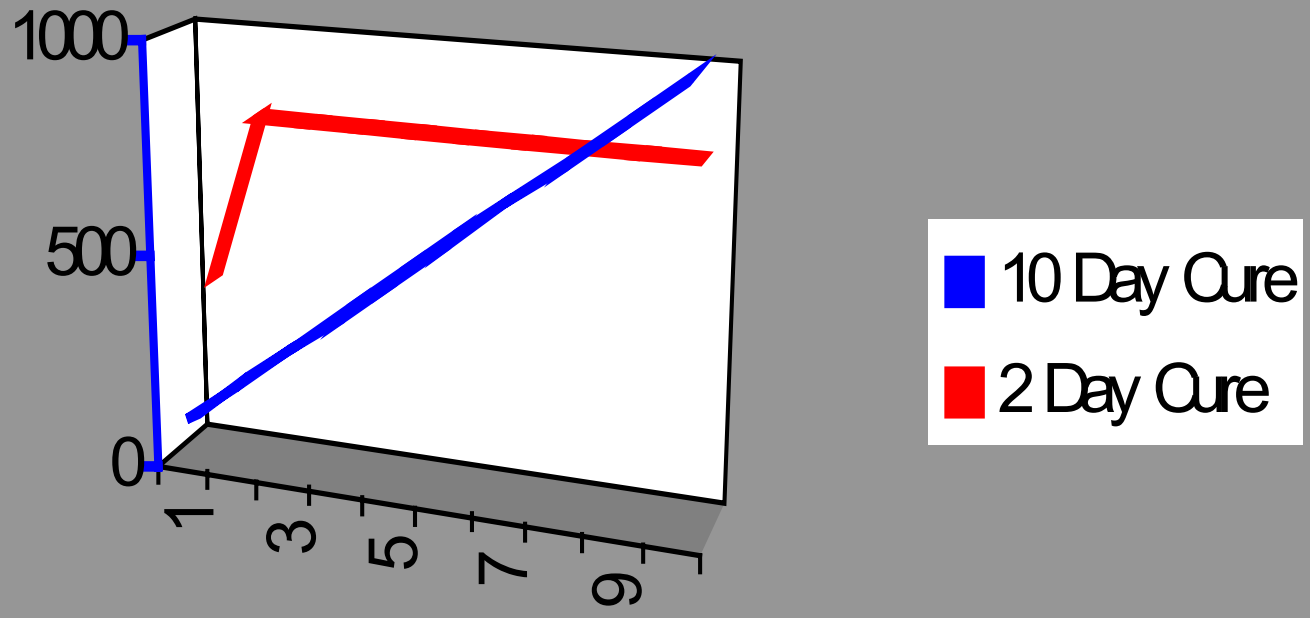
Drug Selection

- Safety
- Clinical Effectiveness
- Cost Impact

Daily Drug Costs



Cumulative Drug Costs



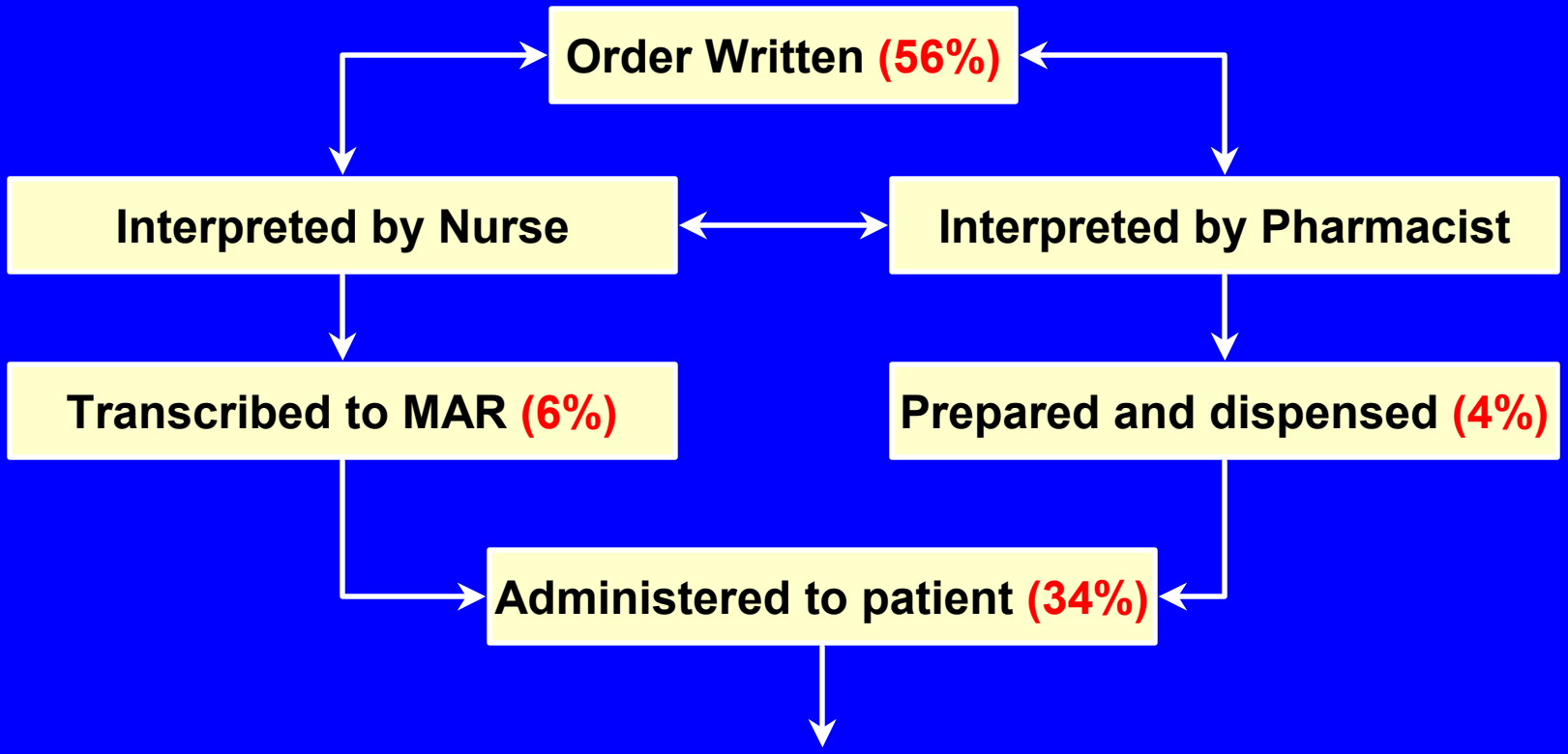
Financial Responsibility at Discharge

	Daily Cost	10 Day Total	Total at Hospital Discharge
2 Day Cure	$400	$800	$800
10 Day Cure	$100	$1000	$300

Perspective Based Financial Responsibility

	2 Day Cure	10 Day Cure
Hospital	$800	$300
Outpatient	$ 0	$700
Payer		
Total	$800	$1,000

Preventable ADE's



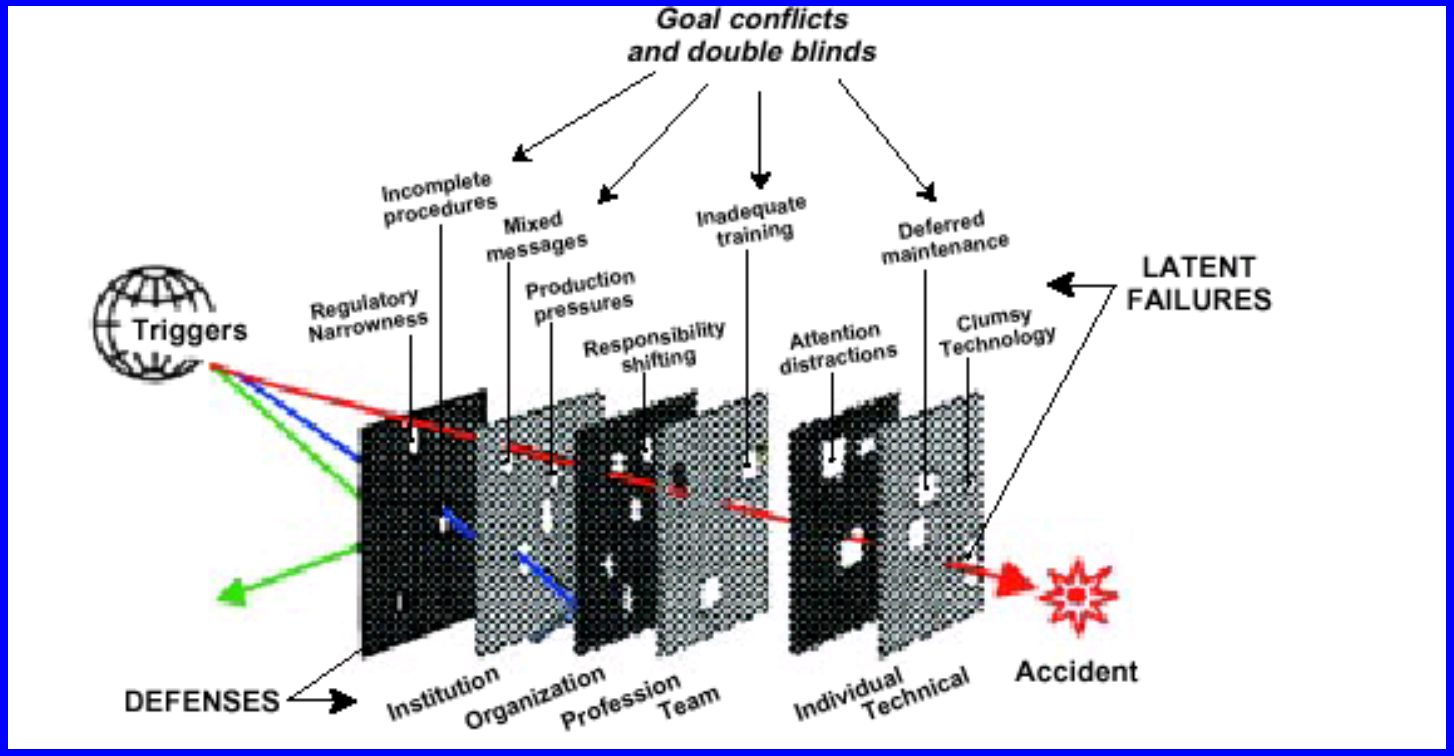
Bates DW, Cullen DJ, et al., JAMA 1995; 274: 29-34

MEDICATION ERROR DEATHS
FDA Adverse Events Reporting System 1993-98

Error Type	%
Wrong dose	41
Wrong drug	16
Wrong route	9.5

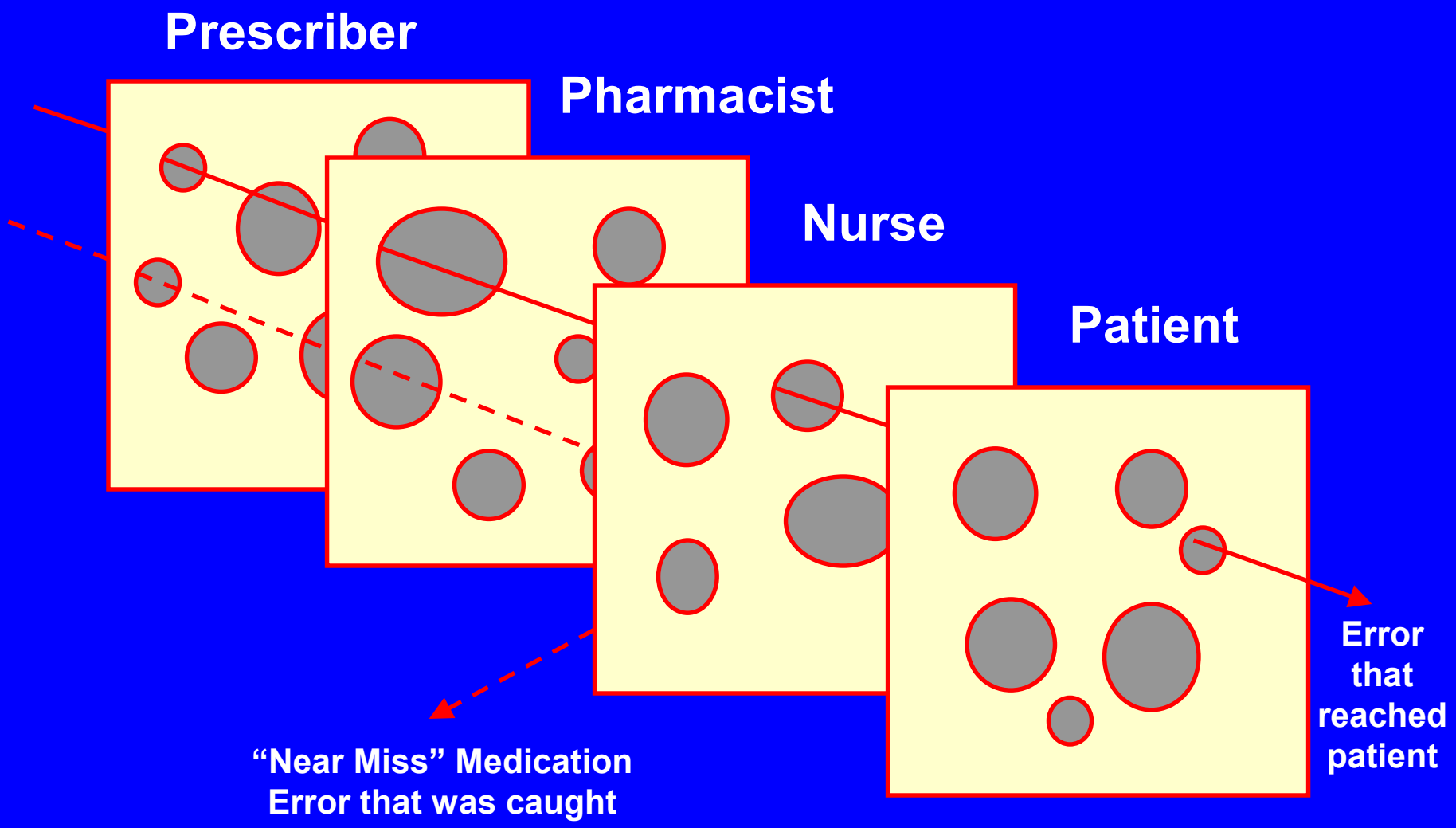
Phillips J, Meam S, Brinker A, et al. Retrospective analysis of mortalities associated with medication errors. Am J Health-sys Pharm, 2001; 58:1835-41.

Sources of Errors and Elements of Defense Against Them



Reason J. Human Error. Cambridge, England: Cambridge Univ. Press; 1990

Defensive Layers in the Medication System

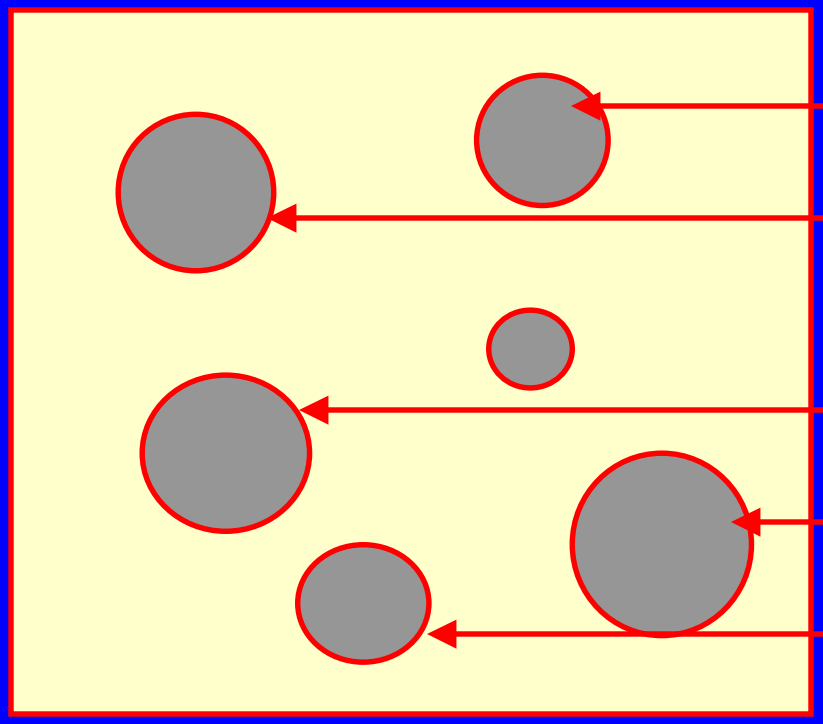


Proximal Causes of Medication Errors*

Lack of knowledge of the drug	Faulty dose checking
Lack of information about the patient	Infusion pump and parenteral delivery problems
Violation of rules	Inadequate monitoring
Slips and memory lapses	Drug stocking and delivery problems
Transcription errors	Preparation errors
Faulty checking of identification	Lack of standardization
Faulty interaction with other services	

* Adapted from Leape LL, et al. Systems analysis of adverse drug events. JAMA 1995;274:35-43

Latent Medication System Errors



Latent Errors

- handwriting
- incomplete information
- order transcription
- unclear labeling
- high workload
- etc

Medication Error Deaths

	1983	1993	Increase %
Analgesics	851	2098	247
Other Central	289	1184	410
Non-tranquilizer Psychotropics	156	315	202

Phillips DP, Christenfeld N, Glynn LM, The Lancet 1998; 351: 643-44

Prescribing Errors by Medication Category

Antimicrobials	40%
Cardiovascular	18%
Gastrointestinal	7%
Narcotic analgesics	7%

Lesar et al. JAMA, 1997

Specific Factors Related to Errors in Medication Prescribing

Decline in renal or hepatic function	13.9%
History of medication allergy	12.1%
Use of abbreviations	11.4%
Incorrect dose calculation	10.8%

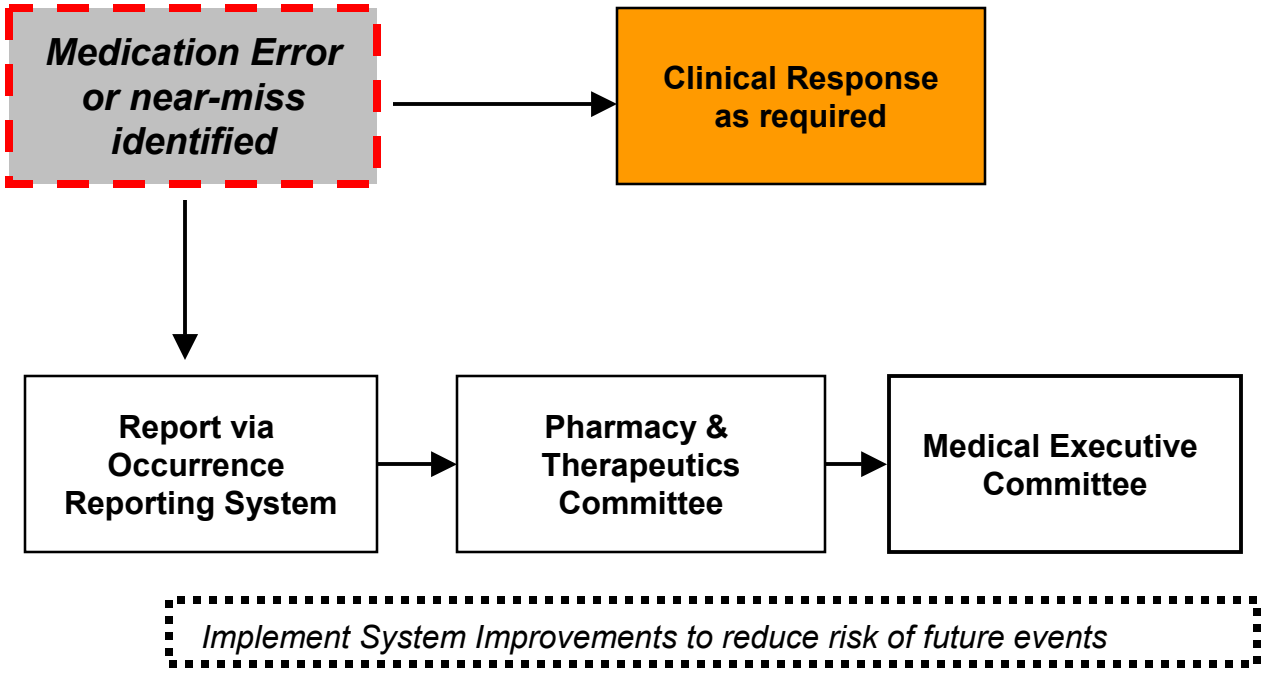
Lesar et al. JAMA, 1997

Safeguard Against Errors in High-Risk Drugs

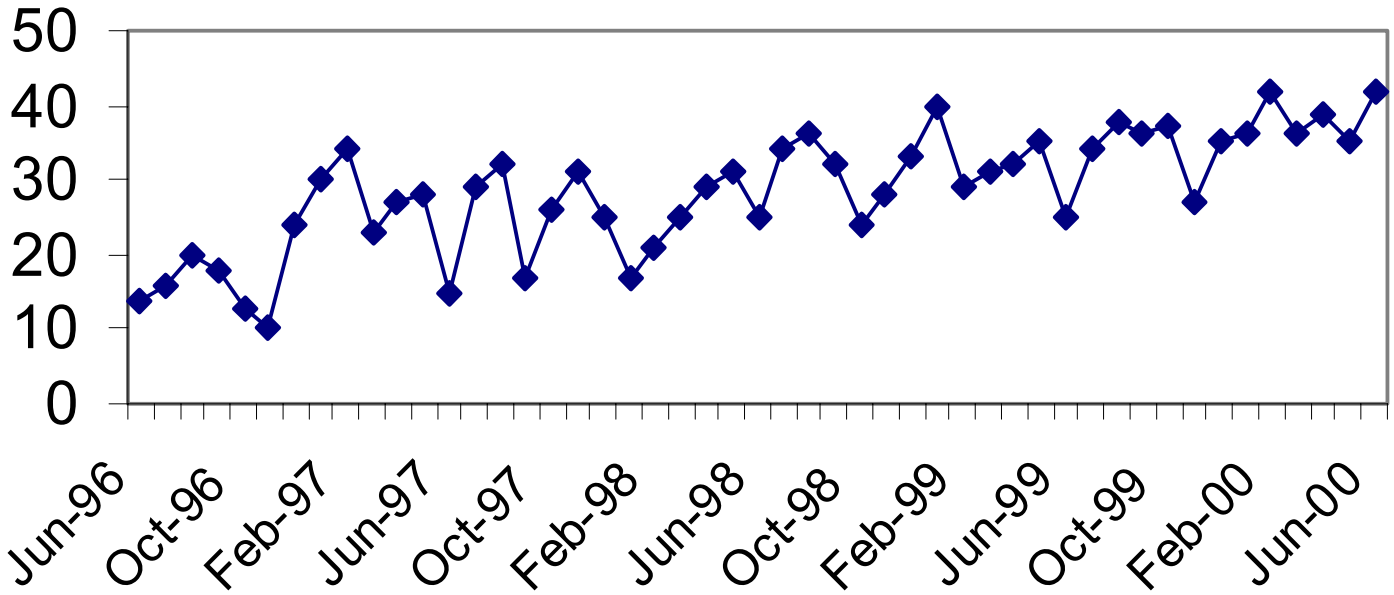
- Build in System Redundancies
- Use Fail-Safes
- Reduce Options
- Use Forcing Functions
- Externalize or Centralize Error-prone Processes
- Store Medications Appropriately
- Screen New Products
- Standardize and Simplify Order Communication
- Limit Access
- Use Constraints
- Use Reminders
- Standardize Dosing Procedures
- Use Differentialization

* Adapted from Cohen MR, Kilo CM. High-Alert Medications: Safeguarding against errors. In Medication Errors. Washington: American Pharmaceutical Association; 1999

Model for Tracking Medication Errors



Total Medication Errors by Month



Use of High Level Data

- Shows interesting trends
- Better for global evaluation
- No detail to work with

Pitfalls of High Level Data

- Cause unclear
- Potential false conclusions

Medication Errors by Quarter

Quarter

	Jun-97	Sep-97	Dec-97	Mar-98	Jun-98	Sep-98	Dec-98	Mar-99	Jun-99	Sep-99	Dec-99	Mar-00	**Mean**
Wrong Drug	5	3	6	2	10	2	4	5	4	8	2	2	4.4
Wrong Dose	11	17	8	13	6	12	18	17	21	15	22	14	14.5
Duplicate Dose	10	4	3	8	2	16	4	11	9	11	6	17	8.4
Wrong Route	3	2	4	0	2	1	1	5	3	0	3	1	2.1
Wrong Time	15	25	12	33	15	19	27	31	17	26	10	29	21.6
Wrong Fluid	6	7	4	10	3	8	7	5	8	2	3	2	5.4
Wrong Rate	16	20	12	17	21	8	24	8	11	19	23	14	16.1
Wrong Device	2	0	0	1	3	1	4	2	0	1	2	2	1.5
IV Infiltration	0	2	1	0	3	2	0	0	4	0	2	0	1.2
TOTAL	**68**	**80**	**50**	**84**	**65**	**69**	**89**	**84**	**77**	**82**	**73**	**81**	**75.2**

Broad-based Information Sources

- Near misses
- Patient specific events
- Aggregated hospital-wide occurrence data
- External medication error data
- Hospital quality improvement data
- Therapeutic trends & changes
- Hospital programatic information

Epidemiology of Medication Errors

- Collect the numbers
- Read between the lines
- Look for common threads
- Try to link together

Medication Use Evaluation

A performance improvement method that focuses on evaluating and improving medication-use processes with the goal of optimal patient outcomes

American Society of Health-System Pharmacists, 1996

Selection of MUE Projects

- known or suspected to cause adverse reactions or drug interactions
- affects large number of patients or medication is frequently prescribed
- potentially toxic or causes discomfort at normal doses
- under consideration for formulary retention, addition, or deletion
- expensive
- used in patients at high risk for adverse reactions
- critical component of care for a specific disease, condition, or procedure
- most effective when used in a specific way
- suboptimal use would have a negative effect on patient outcomes or system costs

•Adapted from American Society of Health-System Pharmacists. ASHP guidelines on medication-use evaluation. Am J Health Syst Phar 1996;53:1953-5.

Review Category	Data Collection Model (s)	Typical Application	Comments
Retrospec	Data is collected for a fixed period which may be archival or accumulation of new patients for a fixed period of time	Data archive search for prescribing patterns of patients on seratonin antagonist antiemetic drugs	Supports large scale epidemiologic approach No active intervention to change medication use patterns occurs due to the post-hoc data collection process
Concurrent	Each new order generates an automatic review of previously approved criteria for use within a specified period of the initiation of therapy	Review of naloxone to investigate possible nosocomial adverse medication event	
	Laboratory or other monitoring criteria are reported for all patients on the drug Abnormal Laboratory or other monitoring criteria are reported for all patients on the drug on a regular basis	Digoxin monitoring based upon daily review of digoxin serum levels (49). Regular review of serum creatinine for patients on aminoglycosides	
Prospective	Each new order for the drug is evaluated for compliance with previously approved criteria for use. Variance to the criteria require intervention prior to initiation of therapy	Medication use guidelines (ketorolac) (50); Restricted antibiotics	

			SPENT FY 95	SPENT FY 96	SPENT FY 97
80000	**ANTI-INFECTIVE AGENTS**				
	80400	AMEBICIDES	$0	$1,522	$332
	80800	ANTHELMINTICS	$2,510	$996	$2,623
	81202	AMINOGLYCOSIDES	$9,457	$13,457	$10,351
	81204	ANTIFUNGAL ANTIBIOTICS	$256,806	$320,884	$357,206
	81206	CEPHALOSPORINS	$221,196	$197,231	$162,850
	81207	B-LACTAMS	$59,322	$77,722	$77,703
	81208	CHLORAMPHENICOLS	$626	$204	$172
	81212	ERYTHROMYCINS	$52,106	$69,377	$89,793
	81216	PENICILLINS	$50,569	$41,427	$65,243
	81224	TETRACYCLINES	$16,872	$4,427	$4,788
	81228	MISCELLANEOUS ANTIBIOTICS	$38,577	$35,347	$35,261
	81600	ANTITUBERCULOSIS AGENTS	$33,141	$27,937	$42,335
	81800	ANTIVIRALS	$658,157	$1,399,246	$2,472,982
	82000	ANTIMALARIAL AGENTS	$82,141	$60,942	$20,848
	82200	QUINOLONES	$82,319	$113,064	$94,705
	82400	SULFONAMIDES	$7,053	$6,730	$3,425
	82600	SULFONES	$5,207	$4,839	$4,651
	83200	ANTITRICHOMONAL AGENTS	$1,493	$3,923	$677
	83600	URINARY ANTI-INFECTIVES	$5,974	$2,009	$2,142
	84000	MISCELLANEOUS ANTI-INFECTIVES	$28,489	$34,661	$30,211
80000	**ANTI-INFECTIVE AGENTS TOTAL**		$1,612,016	$2,415,944	$3,478,297
100000	**ANTINEOPLASTIC AGENTS TOTAL**		$1,226,067	$1,564,834	$1,550,613

Medication Safety Research

Who

- Agency for Healthcare Research & Quality
- FDA
- VA
- Institute for Healthcare Improvement

What*

- Fundamental Research on Errors
- Evaluation of Reporting Systems
- Applied Research in Patient Safety

*Eisenberg, Meyer & Foster 2000

Computerized Order Entry

- Nightingale (BMJ, 2000)
- Bates (JAMA, 1998; JAIMA, 1999)
- Raschke (JAMA, 1998)
- Claussen (Ann Intern Med, 1996)

Drug Name Selection

- Lambert (AJHP, 1997)
- Lambert (Medical Care, 1999)
- FDA Draft Guidance on Evaluating Proprietary Names

Summary of Medication Use Quality Issues

- Complex process prone to error
- Drug use can be improved
- ADE risks can be reduced


GRF
INJECT
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STUDY
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INJECTION